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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 176

[Docket Nos. 94F-0185 and 95F-0111]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine), as a slimicide in the manufacture of paper and paperboard intended to contact food. This action is in response to petitions filed by Great Lakes Chemical Corp. and Lonza, Inc.

DATES: This rule is effective *[insert date of publication in the Federal Register]*. Submit written objections and requests for a hearing by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 14, 1994 (59 FR 30595), FDA announced that a food additive petition (FAP 4B4418) had been filed by Great Lakes Chemical Corp., P.O. Box 2200, West Lafayette, IN 47906-0200. The company is currently represented by Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The Great Lakes petition proposed to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of 1-bromo-3-chloro-5,5-dimethylhydantoin (CAS Reg. No. 16079-88-2) as a slimicide in the manufacture of paper and paperboard intended to contact food.

Thereafter, in a notice published in the **Federal Register** of June 14, 1995 (60 FR 31319), FDA announced that a food additive petition (FAP 3B4382) had been filed by Lonza, Inc., c/o Delta Analytical Corp., 7910 Woodmont Ave., Bethesda, MD 20814. Lonza, Inc., is currently represented by Lewis and Harrison, 122 C St. NW., suite 740, Washington, DC 20001. The Lonza petition proposed to amend the food additive regulations in § 176.300 to provide for the safe use of a mixture of 1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin, and 1,3-dichloro-5-ethyl-5-methylhydantoin as a slimicide in the manufacture of paper and paperboard intended to contact food.

In the filing notice for FAP 4B4418, the additive was identified as 1-bromo-3-chloro-5,5-dimethylhydantoin (CAS Reg. No. 16079-88-2). This nomenclature and this CAS Reg. No. apply to a single discrete substance; however, the additive is actually an equilibrium isomeric mixture of halogenated 5,5-dimethylhydantoin species. Subsequent to the filing of the petition, Great Lakes Chemical Corp. and FDA agreed that the additive is more appropriately identified as 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine).

In the filing notice for FAP 3B4382, the additive was identified as a mixture of 1-bromo-3-chloro-5,5-dimethylhydantoin and 1,3-dichloro-5,5-dimethylhydantoin and 1,3-dichloro-5-ethyl-5-methylhydantoin. However, the additive is actually an equilibrium isomeric mixture of halogenated 5,5-dimethylhydantoin and 5-ethyl-5-methyl hydantoin species. Lonza, Inc., and FDA agreed that

the additive is more appropriately identified as 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine). This description includes the use proposed by both Great Lakes Chemical Corp. and Lonza, Inc. Therefore, this final rule responds to both petitions.

FDA has evaluated data in the petitions and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive, 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine), as a slimicide in the manufacture of paper and paperboard intended to contact food is safe; (2) the additive will achieve its intended technical effect; and therefore, (3) the regulations in § 176.300 should be amended as set forth below.

The additive, 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) intended for use as a slimicide in the manufacture of paper and paperboard intended to contact food is regulated under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) as a food additive and not as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). However, this intended use of 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) may, nevertheless, be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to use food-contact articles containing 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) as a slimicide in the manufacture of paper and

paperboard intended to contact food should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

When both petitions were filed, they each contained an environmental assessment (EA). In the respective notices of filing, the agency announced that it was placing the EA's on display at the Dockets Management Branch for public review and comment. No comments were received on either EA. In addition, prior to completing our review of the EA submitted in FAP 3B4382, Lonza, Inc., submitted a claim of categorical exclusion under 21 CFR 25.32(q).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that this action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by *[insert date 30 days after date of publication in the Federal Register]*. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing

is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.300 is amended in the table in paragraph (c) by alphabetically adding an entry under the headings “List of substances” and “Limitations” to read as follows:

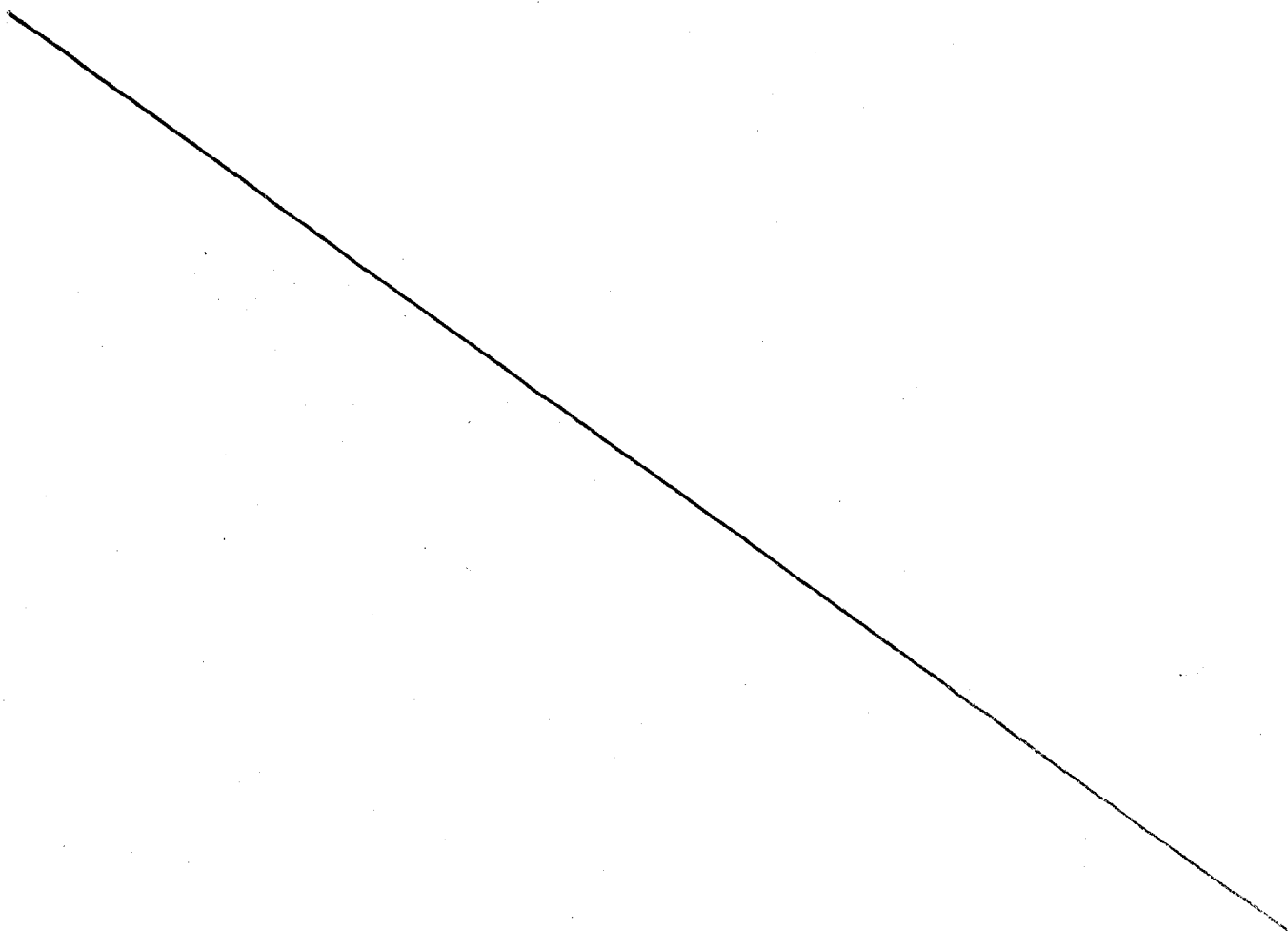
§ 176.300 Slimicides.

* * * * *

(c) * * *

List of substances	Limitations
<p>* * * *</p> <p>1,3-Dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine).</p> <p>* * *</p>	<p>* * *</p> <p>At a maximum level of 1.0 kilogram (kg) per 1,000 kg of dry weight fiber.</p> <p>* * *</p>

* * * *



Dated: 6/15/00

cf99198

L. Robert Lake

L. Robert Lake

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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